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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Pascal Aznar

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41754 7590 06/09/2009  
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EXAMINER

MARTINEZ, BRITTANY M

ART UNIT

PAPER NUMBER

1793

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/536,853	<b>Applicant(s)</b> AZNAR, PASCAL	
	<b>Examiner</b> BRITTANY M. MARTINEZ	<b>Art Unit</b> 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Application*

Applicant's arguments/remarks and amendments filed on February 27, 2009, have been carefully considered. **Claims 1-6** are pending in this application, with **Claims 1 and 2** amended. **Claims 1-6** have been examined.

### *Claim Rejections - 35 USC § 102/103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office action.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1-3** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ren et al. (US 2004/0018260 A1).

3. With regard to **Claims 1-2**, Ren discloses a column for flash chromatography comprising spherical and porous silica gel having 40-63  $\mu\text{m}$  particles with a pore size of 60 angstroms (Ren, p. 4, 0073; p.9-10, 0132). With regard to **Claim 2**, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical

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shape. Thus, a semi-spherical silica granule would be anticipated and obvious in view of the spheres of Ren.

4. With regard to **Claim 3**, Ren discloses a column for flash chromatography containing 100 g of spherical and porous silica gel (Ren, p.5, 0083).

5. **Claims 1-3** are also obvious over Ren because anticipation is the epitome of obviousness.

6. **Claims 1-3** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ramage et al. (US 6,359,113).

7. With regard to **Claims 1-2**, Ramage discloses a column for flash chromatography comprising spherical and porous silica gel having 7  $\mu\text{m}$  particles with a pore size of 300 angstroms (Ramage, c. 7, l. 18-40). With regard to **Claim 2**, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica granule would be anticipated and obvious in view of the spheres of Ramage.

8. With regard to **Claim 3**, Ramage discloses a column for flash chromatography containing 60-100 g of spherical and porous silica gel (Ramage, c. 7, l. 18-40).

9. **Claims 1-3** are also obvious over Ramage because anticipation is the epitome of obviousness.

***Claim Rejections - 35 USC § 103***

1. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ren et al. (US 2004/0018260 A1) as applied to **Claims 1 and 2** above, and further as discussed below.
2. Ren does not explicitly disclose a column for flash chromatography adapted to purify synthetic products in quantities comprised between 10 mg to 100g (**Claim 6**).
3. With regard to **Claim 6**, an expected product quantity to be treated is a result effective variable since one of ordinary skill in the art would expect different properties in the product as such amount varies. Since the product quantity to be treated is a result effective variable, it is within the ordinary skill of one of ordinary skill in the art to develop a suitable synthetic product quantity. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Further, adapting a column to purify various amounts of synthetic products would be a matter of product design and routine optimization.
4. **Claims 4-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ren et al. (US 2004/0018260 A1) as applied to **Claims 1 and 2** above, and further in view of Fuji (XP-002198180).
5. Ren does not explicitly disclose the column manufactured with tubes and syringe bodies or similar forms (**Claims 4 and 5**); nor a column for flash chromatography adapted to purify synthetic products in quantities comprised between 10 mg to 100g (**Claim 6**).

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6. With regard to **Claims 4-5**, it is well-known in the art that columns for flash chromatography are manufactured with tubes and syringe bodies, as evidenced by Fuji (Fuji, p. 1, "Flash chromatography system").

7. With regard to **Claim 6**, Fuji discloses a column for flash chromatography adapted to purify synthetic products in quantities of about 50 mg (Fuji, p. 2, "Loading amount and performance").

8. Thus, it would have been obvious to one of ordinary skill in the art to try to modify the column disclosed by Ren with the column components and product quantities as taught by Fuji because one of ordinary skill in the art could have pursued the known potential flash chromatography column options within his or her technical grasp with a reasonable expectation of success.

9. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramage et al. (US 6,359,113) as applied to **Claims 1 and 2** above, and further as discussed below.

10. Ramage does not explicitly disclose a column for flash chromatography adapted to purify synthetic products in quantities comprised between 10 mg to 100g (**Claim 6**).

11. With regard to **Claim 6**, an expected product quantity to be treated is a result effective variable since one of ordinary skill in the art would expect different properties in the product as such amount varies. Since the product quantity to be treated is a result effective variable, it is within the ordinary skill of one of ordinary skill in the art to develop a suitable synthetic product quantity. *In re Boesch*, 617 F.2d 272, 205 USPQ 215

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(CCPA 1980). Further, adapting a column to purify various amounts of synthetic products would be a matter of product design and routine optimization.

12. **Claims 4-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramage et al. (US 6,359,113) as applied to **Claims 1 and 2** above, and further in view of Fuji (XP-002198180).

13. Ramage does not explicitly disclose the column manufactured with tubes and syringe bodies or similar forms (**Claims 4 and 5**); nor a column for flash chromatography adapted to purify synthetic products in quantities comprised between 10 mg to 100g (**Claim 6**).

14. With regard to **Claims 4-5**, it is well-known in the art that columns for flash chromatography are manufactured with tubes and syringe bodies, as evidenced by Fuji (Fuji, p. 1, "Flash chromatography system").

15. With regard to **Claim 6**, Fuji discloses a column for flash chromatography adapted to purify synthetic products in quantities of about 50 mg (Fuji, p. 2, "Loading amount and performance").

16. Thus, it would have been obvious to one of ordinary skill in the art to try to modify the column disclosed by Ramage with the column components and product quantities as taught by Fuji because one of ordinary skill in the art could have pursued the known potential flash chromatography column options within his or her technical grasp with a reasonable expectation of success.

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17. **Claims 1-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji (XP-002198180).

18. With regard to **Claims 1-2**, Fuji discloses a column for flash chromatography comprising granular and porous silica gel having 42  $\mu\text{m}$  granules with a pore size of 6 nm (Fuji, p. 1, "Properties of FL60D;" p. 2, "Flash chromatogram of BW-300").

19. With regard to **Claim 3**, Fuji discloses a column for flash chromatography containing 25 g of granular and porous silica gel (Fuji, p. 2, "Loading amount and performance").

20. With regard to **Claims 4-5**, Fuji discloses a column for flash chromatography manufactured with tubes and syringe bodies (Fuji, p. 1, "Flash chromatography system").

21. With regard to **Claim 6**, Fuji discloses a column for flash chromatography adapted to purify synthetic products in quantities of about 50 mg (Fuji, p. 2, "Loading amount and performance").

22. Fuji does not explicitly disclose the 42  $\mu\text{m}$  granules being spherical (**Claims 1 and 3**); or semi-spherical silica gel (**Claim 2**).

23. With regard to **Claims 1-3**, the granular silica gel of Fuji would appear to be spherical since silica gel utilized in flash chromatography is generally spherical to allow for ease of packing. It is noted that Applicant's Specification discloses spherical and semi-spherical porous silica gel comprised of "granules" (S. p. 2, "Detailed Description of the Invention") which would presumably be spherical or semi-spherical. Thus, the silica granules of Fuji would be considered spherical no less than the silica of

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Applicant's disclosure. Although Applicant has amended the instant application to replace "granules" with "granulometry," "granulometry" may be interpreted as shape or size since "granulometry" is not in the dictionary. In this case, "granulometry" was interpreted as meaning shape.

24. With regard to **Claim 2**, it is further well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica granule would be obvious in view of Fuji.

25. **Claims 1-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji (XP-002198180) in view of Williams (US 5,559,039).

26. With regard to **Claims 1-2**, Fuji discloses a column for flash chromatography comprising granular and porous silica gel having 42  $\mu\text{m}$  granules with a pore size of 6 nm (Fuji, p. 1, "Properties of FL60D;" p. 2, "Flash chromatogram of BW-300").

27. With regard to **Claim 3**, Fuji discloses a column for flash chromatography containing 25 g of granular and porous silica gel (Fuji, p. 2, "Loading amount and performance").

28. With regard to **Claims 4-5**, Fuji discloses a column for flash chromatography manufactured with tubes and syringe bodies (Fuji, p. 1, "Flash chromatography system").

29. With regard to **Claim 6**, Fuji discloses a column for flash chromatography adapted to purify synthetic products in quantities of about 50 mg (Fuji, p. 2, "Loading amount and performance").

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30. Fuji does not explicitly disclose the 42  $\mu\text{m}$  granules being spherical (**Claims 1 and 3**); or semi-spherical silica gel (**Claim 2**).

31. With regard to **Claims 1-3**, Williams discloses a column for chromatography comprising spherical and porous silica gel having 4.5  $\mu\text{m}$  particles with a pore size of 60 angstroms (Williams, c. 10, l. 59-61).

32. Thus, it would have been obvious to one of ordinary skill in the art to modify the column of Fuji with the silica of Williams in order to obtain a column useful in drug analysis in plasma, serum and urine (Williams, "Abstract").

33. With regard to **Claim 2**, it is further well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica granule would be obvious in view of Fuji.

### ***Response to Amendments***

Applicant's amendments filed February 27, 2009, with respect to the Claims have been fully considered and are accepted.

### ***Response to Arguments***

1. Acknowledgment is made of Applicant's argument that Fuji does not disclose the 42 micron granules being spherical or semi-spherical gel (Applicant's Response, 2/27/09, p. 4); however, Fuji discloses 42  $\mu\text{m}$  granules (Fuji, p. 2, "Flash chromatogram of BW-300") and the granular silica gel of Fuji would appear to be spherical or semi-spherical since silica gel utilized in flash chromatography is generally spherical to allow

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for ease of packing. Further, it is noted that Applicant's Specification discloses spherical and semi-spherical porous silica gel comprised of "granules" (S. p. 2, "Detailed Description of the Invention") which would presumably be spherical or semi-spherical. Thus, the silica granules of Fuji would be considered spherical no less than the silica of Applicant's disclosure. Still further, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica granule would be obvious in view of Fuji.

2. With regard to Applicant's arguments that "granules" has been changed to "granulometry" and granules and spheres are distinct (Applicant's Response, 2/27/09, p. 4-8), it is noted that "granulometry" may be interpreted as shape or size since "granulometry" is not in the dictionary. In this case, "granulometry" was interpreted as meaning shape.

3. Acknowledgment is made of Applicant's Declaration filed December 9, 2008, and discussed in Applicant's February 27, 2009, response (Applicant's Response, 2/27/09, p. 8-10). The Declaration statements concerning the desirability of reduced pump pressure requirement, reduced back pressure (typically associated with increased particle size), and improved resolution of separation materials are acknowledged. Further acknowledgment is made of the evidence provided in the Declaration concerning the unexpected result of sufficiently low back pressure in glass and plastic columns while maintaining high separation resolution, and the experiment performed using the equipment of Fuji with the claimed granule size, shape, and pores.

Acknowledgment is made of the significant improvement in separation resolution of the

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instant application over the results in Fuji, as evidenced by the Declaration (Declaration, 12/9/08, p. 3, Table).

### ***Conclusion***

1. No claim is allowed.
2. In general, prior art renders the claimed invention anticipated and obvious.
3. Applicant is required to provide pinpoint citation to the specification (i.e. page and paragraph number) to support any amendments to the claims in all subsequent communication with the examiner. **No new matter will be allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRITTANY M. MARTINEZ whose telephone number is (571) 270-3586. The examiner can normally be reached Monday-Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached at (571) 272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Wayne Langel/  
Primary Examiner, Art Unit 1793

BMM

/Brittany M Martinez/  
Examiner, Art Unit 1793